1. PURPOSE

To outline requirements and processes for Investigator and Key Personnel education and training.

2. SCOPE

This SOP applies to all human subject research (exempt and non-exempt) at Advocate Aurora Health (AAH), AAH facility or utilizing AAH patients or their individually identifiable data.

3. DEFINITIONS

See Glossary

4. APPLICABLE POLICY STATEMENTS

This SOP implements requirements at section IV.D.1.c) and IV.D.2.h) of AAH System Policy– *Research Involving Humans or Their Identifiable Data or Biospecimens*.

5. PROCEDURES

5.1 Initial Training

a) *What is Required and When*

i) Investigators and Key Personnel listed on human subject research submission for exempt or non-exempt human subject research must complete Collaborative Institutional Training Initiative (CITI) education modules. This education must be completed prior to submitting a study or Change form to the IRB for review. See *Instructions for CITI Training* on the RSPP website.

ii) Additional training may be mandated by the Research, the study's Principal Investigator, and/or study sponsor.

iii) Training is not required for those engaged solely in non-research activities (i.e., clinical use of a Humanitarian Use Device, clinical Expanded Access use and Emergency Use of an investigational agent for clinical purposes). Clinicians should familiarize themselves with requirements related to these activities by reviewing RSPP guidance on the relevant topic.

b) *Documentation & Monitoring of Training*

i) Documentation of training occurs electronically upon completion of the CITI modules. No action on the part of the Investigator or Key Personnel is required.

ii) RSPP Team Member will review initial training documentation to ensure completion prior to accepting an application for IRB review. Investigators and Key Personnel who do not complete initial training will not be approved to engage in human subject research.

5.2 Ongoing Training

a) *What is Required and When*

i) Renewal CITI training is required every three years. See *Renewal Instructions for CITI Training* on the RSPP website.

ii) Additional training may be mandated by the Research Institute, the study's Principal Investigator, and/or study sponsor. The IRB may also require additional training as part of a corrective and preventative action plan part of a Noncompliance or UPIRSO review.

b) *Documentation & Monitoring of Training*

i) Documentation of training occurs electronically upon completion of the CITI modules. No action on the part of the Investigator or Key Personnel is required.

ii) CITI reminds (via the sending of an email) Investigators and Key Personnel of the need for completion of renewal training 90 days (and periodically thereafter) prior to CITI training expiration. Also as a service to key research personnel, AAH IRBNet tracks and records CITI training completion and expiration if the investigator adds their training records to IRBNet.

iii) When it has been brought to the attention of the RSPP that an Investigator or Key Personnel does not complete the required renewal training by the last day of the month in which their CITI expiration date occurs, the RSPP Director or delegated Team Member will notify the individual, a member of Research leadership, and the PI(s) of all open research studies on which the individual participates, that the individual will be removed from participation after 5 business days if the refresher CITI training remains incomplete. The notification to the study PI and

Research Institute leadership will include instruction on the need for replacing the individual, relative to the needs of the research, with someone who is properly trained, so as to not place enrolled subjects at increased risk of harm. If the RSPP office is notified by the PI or Research leadership that enrolled subjects will be placed at increased risk of harm by the removal of the noncompliant Investigator or Key Personnel, the Institutional Official will be consulted, and an action plan devised.

iv) If, after 5 business days, the CITI refresher training remains incomplete, and the RSPP Office has not received notification that removal of the noncompliant individual will cause an increased risk of harm to enrolled subjects, the RSPP Office will complete a *Changes* form removing the individual from all open research studies on which he/she participates. The change will be approved by the RSPP Director or other IRB member. The change will be documented in the RSPP database, and the approved form provided to the individual, the study PI(s), and a member of Research leadership. The noncompliant Investigator or Key Personnel will only be approved for participation in human subject research following completion of the required refresher CITI training.

v) If the noncompliant individual is a study PI, the RSPP Office will immediately notify Research of the need to replace the PI or close the study within 30 days. If replacement of the PI or his/her completion of required training does not occur within 30 days, the issue will be scheduled for convened IRB or expedited review, as appropriate. The IRB or expedited reviewer will consider the effect of an absent PI on subject safety and study integrity and will make a determination as to how long the study may continue without a PI. The sponsor of the study should be immediately notified of the issue.

5.3 Retention

RSPP team members will retain all training records in accordance with AHC system – *AAH Record Retention, Storage and Destruction*

CROSS REFERENCES:

RSPP SOPS: #1 – *Initial Submission*

#3 - *Post-Approval Responsibilities & Submissions*

	RSPP Guidance - *Deferral/Ceding Of IRB Oversight To An External IRB* AAH System Policy– *Research Involving Humans or Their Identifiable Data or Biospecimens*
OWNER:	Director, Research Subject Protection Program
REFERENCES:	AAHRPP Elements I.1.E. and III.2.A.; Standard I-2
PRIOR REVIEW / REVISION DATES:	10/7/21 (effective 11/3/21)